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(54) Title: INSERTION DEVICE WITH PIVOTING ACTION

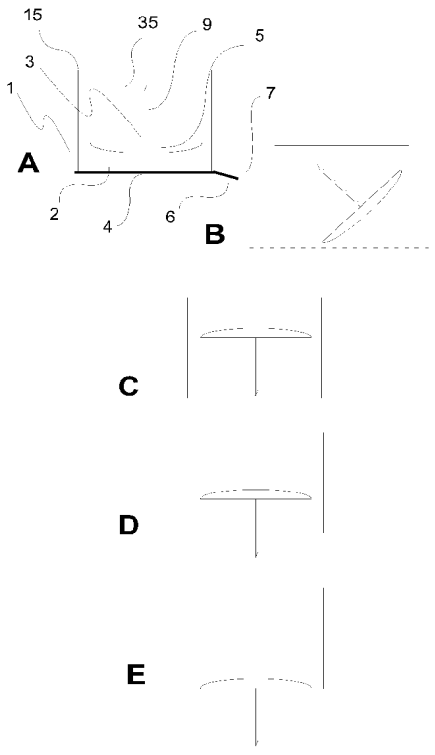

Fig. 1

(57) Abstract: The invention concerns an insertion device for inserting a medical device into the subcutaneous or intramuscular area of a patient. More specifically, this invention relates to an insertion device comprising pivoting and guiding means for moving a penetrating member from a position, where the penetrating member is not pointing into the direction of insertion, to a position, where the penetrating member is pointing into the direction of insertion. The inserter device comprises a housing (15) encompassing a penetrating member (9), said housing comprising a top section (14) and a lower section (16), wherein said insertion device (1) comprises pivoting means (27, 31, 41, 43) and guiding means (10, 19, 16s, 31s, 18s) providing one or more pivoting movement(s) of the penetrating member (9) from a first position, where the penetrating member (9) is not pointing into the direction of insertion, to a second position, where the penetrating member (9) is aligned with the direction of insertion, to a third position, where the penetrating member (9) protrudes the housing (15) and the penetrating member (9) is aligned in the direction of insertion. The guiding means (10, 19, 16s, 31s, 18s) are adapted to provide a longitudinal movement of the penetrating member (9) from the second to the third position.

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INSERTION DEVICE WITH PIVOTING ACTION

Technical field of the invention

The invention concerns an insertion device for inserting a medical device into the subcutaneous or intramuscular area of a patient. More specifically, this invention relates to an insertion device comprising pivoting and guiding means for moving a penetrating member from a position, where the penetrating member is not pointing into the direction of insertion, to a position, where the penetrating member is pointing into the direction of insertion.

Background of the invention

Insertion devices, also called injectors, are commonly used in the medical field for inserting medical devices such as infusion sets and the like, in a semi-automated fashion through the skin of a patient.

EP 1 011 785 relates to an injector for a subcutaneous infusion set, EP 1 044 028 concerns an insertion device for an insertion set.

EP 1 502 613 relates to an inserter device for inserting a penetrating member into the subcutaneous area of a patient. The penetrating member according to this inserter device performs a curved movement during the insertion i.e. the penetrating member continuously changes direction even after the point of the penetrating member has penetrated the skin surface of the patient. This curved movement can cause discomfort or even pain to the patient.

It is known that any patients, especially children, are afraid of sharp objects, such as injection needles and other penetrating devices, commonly used for medical treatment and therapy. This fear is often irrational, and it may hamper an appropriate medical treatment. For example in the case of self-medication, a lack of administration of an appropriate dose of a required

medical composition can lead to complications, which may even be life-threatening. When treating diabetes, e.g. in juveniles, there is a risk that the required insulin-dose may not be self-administered due to irrational fear of the device's needle, combined with a general lack of knowledge and awareness concerning the consequences of omitting the correct application of the device and dosage.

A further known issue with insertion of medical devices is the risk of contamination of the penetrating member before or during application. This can easily lead to the introduction of an infection to a patient, e.g. through a contaminated insertion needle. The longer such a needle is exposed, the higher the risk of accidental contamination, e.g. by touching the needle with a finger, bringing the needle in contact with an unclean surface, or by airborne contamination, aerosol contamination and the like. Depending on the nature of the contamination (e.g. comprising virus, bacteria, fungus, yeast and/or prion) combined with the general health status of the patient, the resulting infection can rapidly turn into a life threatening situation.

Finally, it is well known that contact with an infected, used needle especially in hospital environments can be life-threatening, and the risk of accidental exposure to contaminated material must be minimized.

Thus, there is an obvious need in the art for a robust, reliable, accurate, safe, and user friendly insertion device, which addresses the issues discussed above.

Summary of the invention

The current invention provides an insertion device, where the penetrating device, such as needle or cannula or both, are not visible prior, during and after insertion of the medical device, whereby administration and handling is drastically facilitated, and user friendliness is improved. Further this device

reduces the risk of infections and contaminations, due to the absence of an exposed penetrating device. When applicable, the medical device's insertion needle is retracted into the housing of the insertion device, thus facilitating handling and disposing of the medical device in question.

Thus, the present invention provides an insertion device as defined by claim 1 for inserting a penetrating member into the subcutaneous area and/or intramuscular area of a patient, said inserter device comprising a housing encompassing the penetrating member, which housing further comprises a top section and a lower section. The insertion device also comprises pivoting means and guiding means for providing one or more pivoting movement(s) and one or more longitudinal movement(s) of the penetrating member from a first position, where the penetrating member is not pointing into the direction of insertion, to a second position, where the penetrating member is aligned with the direction of insertion but not protruding said housing, to a third position, where the penetrating member protrudes the housing and the penetrating member is aligned in the direction of insertion.

The pivoting and guiding means can also provide a fourth position by a longitudinal movement in which position the penetrating element is fully inserted in the patient, where the longitudinal movement being of the same length or longer than the length of the penetrating member.

According to one embodiment the pivoting means comprise one or more shafts. This shaft can traverse the top section and/or the lower section. E.g. the shaft can consists of one through-going member or the shaft can consists of two or more pieces.

According to one embodiment the device mounting means, on which the medical device are attached, are attached to said shaft, and the device mounting means and the shaft share the same center of rotation.

According to one embodiment the pivoting means comprise one or more pivoting shafts and one or more pivoting members. E.g. a first pivoting shaft can traverse the lower section and a pivoting member, and the first pivoting shaft is the centre of rotating of said pivoting member. Further a second pivoting shaft can traverse the pivoting member and the device mounting means.

According to one embodiment the guiding means comprise one or more guiding slots. These guiding slots can be provided on the lower section where the guiding slots can be parallel to the direction of insertion, and are of the same length or longer than the length of said longitudinal movement. The guiding slots can be encompassing the shaft, and restrict the length of the longitudinal movement of the shaft and the lower section.

The guiding slot can be provided within a pivoting member, where the guiding slot comprises a bend section towards the upper part of the pivoting member, and a straight section of the same length or longer than the length of said longitudinal movement. The guiding slot encompasses and restricts the movement of said shaft.

The guiding slot can be provided within a vertical section of the device mounting means. The guiding slot is then of the same length or longer than the length of said longitudinal movement, and the guiding slot encompasses the second pivoting shaft, and restricts the movement of the second pivoting shaft.

According to one embodiment the application of a downward force on the top section into the direction of insertion provides a rotation of the medical device through interactions of the shaft being guided by the guiding slot of the lower section and the guiding slot of the pivoting member, and through interactions of the first and second pivoting shafts being guided by the pivoting member and guiding slot on the vertical section of the device mounting means.

According to one embodiment the guiding means comprise one or more rounded protrusions provided on the device mounting means, said protrusions extending away from the direction of insertion. The guiding means comprise a major protrusion flanked symmetrically by two minor protrusions, where the major protrusion is aligned with the penetrating member along an axis perpendicularly to the shaft. According to this embodiment the device can comprise upper guiding means and lower guiding means, where the upper and lower guiding means are extending from the inner surface of the lower section. Upon application of a downward force on the top section the interaction between the protrusions and the upper and lower guiding means provides a rotation of the medical device.

According to one embodiment the penetrating member comprises a cannula and/or an introducer needle. If the introducer needle is part of the inserter device, then the introducer needle is removed from the medical device after insertion of the penetrating member.

According to one embodiment the pivoting and guiding means can provide a fifth position by a longitudinal movement, optionally accompanied by a pivoting or rotational movement, where the introducer needle is retracted through the cannula. This fifth position can be provided by one or more linear movements and one or more pivoting movements, where the needle is retracted into the housing. The device can be constructed in a way where the introducer needle is no longer visible after retraction into the housing.

According to one embodiment the penetrating member is a part of a medical device e.g. the penetrating member consist of a hard penetrating cannula.

According to the invention the medical device can be a sensor, or an infusion part, or a gateway/port for injection of a fluid.

According to the invention the inserter device can either be for single use (disposable) or be suitable for repeated use e.g. depending on the materials used to construct the device.

According to the invention the inserter device can be suitable for inserting different medical devices, either simultaneously or consecutively.

According to the invention the inserter device can be cleaned, disinfected and/or sterilized before, after or in between uses.

According to the invention the inserter device can comprise a penetration member which is "in center" or "off center" of the inserter device.

According to the invention the inserter device can comprise additional cover and/or protection means.

According to the invention the inserter device can have a central axis of insertion which is parallel to the central axis of the insertion device.

According to the invention the inserter device can have a central direction of insertion of the penetrating member which is either essentially perpendicular to the patient's skin, i.e. has an insertion angle α_{ins} around 90°, or have an insertion angle $0° < \alpha_{ins} < 90°$, or $10° < \alpha_{ins} < 80°$, or $20° < \alpha_{ins} < 70°$.

According to the invention the inserter device can have a center axis of the inserter device which is essentially perpendicular to the patient's skin, i.e. has a center axis angle α_{center} around 90°, or at an center axis angle $0° < \alpha_{center} < 90°$, or $10° < \alpha_{center} < 80°$, or $30° < \alpha_{center} < 60°$.

According to the invention the inserter device can have a direction of insertion of the penetrating member which is either parallel to the center axis

of the inserter device, i.e. has a deflection angle $\alpha_{defl} = 0°$, or has a deflection angle $0° < \alpha_{defl} < 90°$, or $10° < \alpha_{defl} < 80°$, or $30° < \alpha_{defl} < 60°$.

Brief description of the drawings

A detailed description of embodiments of the current invention will be made with reference to the accompanying figures, wherein like numerals may designate corresponding parts in different figures.

Figure 1: Schematic representation of different positions of a medical device within an insertion device.

Figure 2: Schematic representation of a medical device which can be inserted with the insertion device.

Figure 3: Schematic representation of an insertion device.

Figure 4: Schematic representation of an insertion device.

Figure 5: Schematic representation of an insertion device with shielding means.

Figure 6: Cross section of an embodiment of an insertion device with pivoting and guiding means. A: before insertion; B: cannula inserted.

Figure 7: Pivoting and guiding means and their relative positions during insertion (positions I-VI).

Figure 8: Another view of pivoting and guiding means and their relative positions during insertion (positions I-VI).

Detailed description of the invention

Figure 1 shows an insertion device 1, and illustrates different positions of a medical device 3 within the main cavity 35 of the insertion device 1; said medical device 3 comprises a penetrating member 9, according to the current invention. The main cavity 35 is defined as the volume within the housing 15 of the insertion device 1 and a bottom plane 7, illustrated by a stippled line. The main cavity 35 is sufficiently dimensioned, in width, height and diameter, and optionally flexible and/or variable in size to encompass a medical device

3 comprising a penetrating member 9, and to allow for one or more rotations and/or pivoting movement, and optionally, one or more longitudinal movements (Figure 1).

The insertion device according to the invention comprises an opening 2 towards the bottom plane 7 of the housing 15. Said opening is as wide as, or wider than the body 5 of the medical device 3 to be inserted. The embodiment of an insertion device 1 shown in Figure 1 comprises an opening 2, which is sufficiently wide to allow the medical device 3 to leave the insertion device 1 through said opening 2. Often, the opening 2 can be sealed with a detachable sealing foil or release liner, which can comprise a flap 6 in order to facilitate the removal process before use of the insertion device. This may ensure an appropriate hygiene standard, such as maintaining appropriate levels of disinfection or sterility. Furthermore, the sealing foil may act as an indicator for integrity of the insertion device 1 and/or medical device 3, thereby improving safety standards, as use of potentially compromised and thus no longer sterile device can be avoided.

In the start position according to the embodiment of the invention depicted in Figure 1 A, the penetrating member 9 of the medical device 3 is turned 180° away from the direction of insertion. The direction of insertion being equivalent to 0° is in this example perpendicular to the bottom plane 7. In this case the penetrating member 9 is pointing upwards, as depicted in Figure 1 (position A). The penetrating member 9 is not visible in position A when looking into the main cavity 35, as the penetrating member 9 is shielded by the body 5 of the medical device no matter how small the body 5 of the medical device is. In another embodiment, the medical device is turned away from the direction of insertion at an angle of around 135° in the start position. In a further embodiment, the medical device is turned away from the direction of insertion at an angle between > 0° and 180°, and the insertion device is

not visible and/or shielded by the housing 15 and/or the body 5 of the medical device 3.

According to the invention, the insertion device comprises pivoting and guiding means for providing a 2nd position, position C, at this position the medical device 3 - including the penetrating member 9 - is still within the main cavity 35, thus not protruding the insertion device 1, and the medical device and the penetrating member 9 are aligned in the direction of insertion (Figure 1).

Via a 3rd position, position D, where at least a part of the penetrating member 9 protrudes the housing 15, the insertion device arrives at a 4th position, position E, where the penetrating member 9 is fully extended. This extending of the penetrating member 9 is achieved by an essentially longitudinal movement in the direction of insertion, which is at least as long as the length of the penetrating member 9 as the penetrating member 9 has to be inserted in full length.

Figure 2 illustrates an embodiment of a medical device 3 which can be inserted with an inserter device according to the invention. Commonly, such a medical device 3 comprises a body 5, which is not inserted into the patient but rests on the patient's skin, and one or more penetrating members 9. The medical device depicted in Figure 2 is a port device set possessing a penetrating member 9 comprising a soft cannula 11 and an introducer needle 13. In case of a soft cannula, which cannot be inserted without aid of e.g. an insertion needle, the insertion needle is retracted upon application of the medical device. This may require attachment means 23 for manual retraction of the introducer needle 13, which are also shown in Figure 2. Other medical devices may comprise a cannula with penetrating ability which remains inserted in the patient upon application of the medical device.

Medical devices that can be inserted according to the invention comprise e.g. infusion sets or the infusion part of an infusion set, sensor devices comprising one or more inserted sensors, port devices which only comprises a body with a restricted access for replacing repeated injections with syringes or any other device which has a penetrating member inserted into the subcutaneous area or intramuscular area of a patient

Often, a mounting pad is used to ensure the appropriate contact of the medical device with the skin of the patient. This mounting pad may be attached to the underside of the body 5 of the medical device 3. Alternatively, the mounting pad is attached to the skin of the patient, and the medical device is inserted directly through the mounting pad, or through an opening in the mounting pad. Generally, the mounting pad's adhesive strength is sufficiently strong to ensure that the medical device remains on the skin of the patient after insertion, and only the insertion needle 13 is removed through the cannula 11, while the medical device remains in place. In an alternative embodiment of the current invention, the medical device 3 is inserted through a second medical device.

Figure 3 depicts a further embodiment of the invention. Figure 3A shows a housing of an insertion device according to the invention. The housing of the insertion device 1 comprises to sections, a top section 14 and a lower section 16, both essentially in the shape of a hollow cylinder jacket; the two sections can have any cross-section e.g. cylindrical as shown in Figure 3, or elliptic or polygonal e.g. square as long as the top section 14 and the lower section 16 corresponds to each other. Top section 14 is closed at the top via a top surface 7. The diameter of the top part 15 is wider than the diameter of the lower section 16, and the two sections are about similar in height, and the top section 14 overlaps the lower section 16.

Towards the lower part of top section 14, attachment means 29 comprising a through-going hole and optionally a bearing are provided for attaching

rotating/pivoting means. The rotating/pivoting means comprises a cylindrical aperture or bearing for a rotating/pivoting shaft 27, which is mounted within the top section 14. The attachment means 29 are situated symmetrically, and optionally diametrically.

The lower section 16 is neither closed at the top or at the bottom, and comprises a pair of symmetrical guiding slots 10 positioned vertically, i.e. parallel to the direction of insertion and symmetrically across a diagonal line across the lower section 16. The guiding slot 10 is dimensioned sufficiently wide to provide guiding of the rotating/pivoting shaft 27 and to allow a longitudinal movement of the rotating/pivoting shaft 27 along the guiding slot 10. Top section 14 and lower section 16 are connected via said rotating/pivoting shaft 27.

Figure 3B shows a top view of a medical device 3 with the penetrating member 9 pointing towards the observer. The proximal side of the body 5, i.e. the side facing the skin of the patient, upon application of the medical device 3 is seen, as well as a mounting pad 6. The ends of the pivoting/rotating shaft 27 that are protruding the mounting pad 6 are visible.

Figure 3C shows a view of a cross section along or parallel to the pivoting/rotating shaft 27 of the insertion device 1, whereby further constituents and features become apparent. The penetrating member 9 of the medical device 3 is pointing up (i.e. position 1, Figure 1) towards the closed circular top surface 7 of the top section 14. The medical device 3 is attached in a releasable fashion to a pivoting/rotating shaft 27 via device mounting means 18. According to one embodiment of the invention, medical device 3 is attached to the device mounting means 18 via the introducer needle 13 and the friction between said introducer needle 13 and the cannula 11. The introducer needle 13 is retracted upon insertion of the medical device 3. The friction between introducer needle 13 and cannula 9 provides sufficient and appropriate attachment between the device mounting means 18 and the medical device 3 before and during insertion. Sufficient and

appropriate attachment means that the medical device 3 does not e.g. slide off or fall off the device mounting means 18 or introducer needle 13 unintendedly - such as before application (including production, sterilization, transport and storage) or during application, which includes the centrifugal force(s) that are induced by the one or more rotational and/or pivoting movements during insertion. Sufficient and appropriate attachment means also, that the friction is not too high, allowing for retraction of the penetrating needle 13 after insertion. Thus the dimensions of the outer diameter of the introducer needle 13 and the inner diameter of the cannula 9, as well as their surface properties are dimensioned and selected accordingly. According to another embodiment of the invention, the medical device 3 is attached to the device mounting means 18 and/or pivoting/rotating shaft 27 via adhesive means. The function of the adhesive means is to provide sufficient and appropriate attachment/adhesion between the medical device 3 and the device mounting means and/or pivoting/rotating shaft 27 that the medical device remains securely attached before and during insertion, but allowing release of the medical device 3 upon insertion. The adhesive means are selected and dimensioned accordingly.

A cross section of the device mounting means 18 is shown in Figure 3C. The pivoting/rotating shaft 27 is either extending through the device mounting means 18, or two independent pivoting/rotating shafts 27 are mounted symmetrically and aligned in the same pivoting/rotating axis on each side of the device mounting means 18. A pair of guiding means 19 is attached on the opposite face of the device mounting means 18, that is, with respect to the medical device, the face pointing 180° away from the direction of insertion of the penetrating member 9. The guiding means 19 are positioned symmetrically towards the outer extremity of the device mounting means, and their distance exceeds the diameter of the medical device 3. In position 1, the pivoting/rotating shaft 27 is parallel to the top section's 14 top surface 7 as well as to the lower section's 16 opening 2, which in this embodiment is closed by a sealing device 4. In an alternative embodiment of the invention,

the sealing device may be a mounting pad. In the depicted embodiment, the guiding slot 10 extends across approximately 2/3 of the height of the lower section 16. Alternatively, the guiding slot 10 can of similar length as the length of the penetrating member 9 or longer. The guiding slot 10 has an upper 10u and a lower end 10l. The pivoting/rotating shaft 27 extends through the guiding slot 10 and through the opening 29 of the top section 14. The height of the top section 14 and lower section 16 exceed each the length of the medical device 3.

Upper guiding means 19u and lower guiding means 19l are provided, which extend perpendicularly from the inner surface of the lower section 16, and essentially parallel to the top surface 7. In one embodiment of the invention, upper and lower guiding means 19u and 19l are cylindrical. In another embodiment of the invention, upper and lower guiding means 19u and 19l are essentially elliptical in diameter. In a further embodiment, and lower guiding means 19u and 19l have a square diameter, optionally with rounded edges. Upper and lower guiding means 19u and 19l are positioned below the device mounting means and guiding means 19, when the medical device 3 is in position 1. The length of the upper and lower guiding means 19u, 19l is sufficient to enable contact with the guiding means 19 upon lowering the device mounting means. A helical spring 25 having a diameter of approximately the outer diameter of the lower section 14, is placed between on the inside of the top section 16 and the lower section 14. The helical spring 25 may be attached to the inner surface of the top section 16 and/or the circular top surface 7. Furthermore, the helical spring 25 may rest and/or be attached to a distal surface, e.g. the top surface 20 of the wall of the lower section 14. When the insertion device is in position 1, the helical spring 25 is in an essentially relaxed state, or close to a relaxed state. The action of the helical spring 25 provides a close to maximal separation of top and lower sections 14, 16, combined with a near maximal volume of their combined cavities, and maintains the medical device in a position, with the penetrating member 9 pointing upwards, i.e. position 1 according to Figure 1.

Figure 3D shows the insertion device in a fully inserted position corresponding to the 4th position is seen in Figure 1E, where the medical device 3 has rotated 180°, the penetrating member 9 and body 5 protrude top and lower sections 14, 16, and the penetrating member 9 will be fully inserted when the insertion device is placed close against the patients skin. When applying a force, e.g. by applying a pressure on the top section 14 in the direction of insertion against the lower section 16, the helical spring 25 will be energized and compressed between the top surface 7 and the top surface 20 of the wall of the lower section 16. The top and lower sections 14, 16 have been set in motion towards each other, thus minimizing the volume of the main cavity 35. The rotating/pivoting shaft(s) 27 - onto which the device holding means comprising guiding means 19 are attached - has moved down the lower end 10l of guiding slot 10, in the direction of insertion of the device, and has passed the upper and lower guiding means 19u, 19l. The consecutive or combined actions and interactions of the guiding means 19, 19u, 19l and rotating/pivoting means 27, 18, 29, combined with a forward motion, have provided a pivoting/rotation of the medical device 3 of approximately 180°, combined with a longitudinal movement. Consequently, the guiding means 19 are now below the upper and lower guiding means 19u, 19l. As depicted in the embodiment presented in Figure 3D, the guiding means 19 - situated on the device mounting means 18 - and 19l are in contact with each other.

Helical spring 25 is selected and dimensioned according to its function. One function of the helical spring 25 is to provide sufficient energy to separate top section 14 and lower sections 16 after insertion of the penetrating member 9 of the medical device 3. According to one embodiment of the invention, the helical spring 25 provides sufficient energy to separate the medical device 3 from the insertion device after insertion, and optionally to return the device mounting means 18 and pivoting/rotating shaft 27 back into the start position,

or into a position close to the start position, such as positions A and B in Figure 1. According to another embodiment of the invention, the helical spring 25 provides also sufficient energy to retract penetrating needle 13 after insertion into a patient.

Figure 4 shows a view of a longitudinal cross section perpendicular to the pivoting/rotating shaft 27. Figure 4 illustrates a similar embodiment as shown in Fig. 3 but from an angle perpendicular to the view angle of Fig. 3. In Figure 4 the abovementioned actions and interactions of the respective guiding and pivoting/rotating means are shown in more details.

The insertion device 1 comprises an top section 14 and a lower section 16, where the top section 14 is wider than the lower section 16, and the top section 14 overlaps at least in part the lower section 16. Their shape (cross-section perpendicular to the longitudinal axis of the insertion device may be cylindrical, elliptical, rectangular, or comprise a combination of round and linear profiles). In one embodiment of the invention, the cross section is rotational-symmetrical, or symmetrical across at least one diagonal line, such as mirror symmetrical (not shown).

Figure 4 shows essentially the same features as Figure 3. However, in this embodiment, the device mounting means 18 comprise guiding means 19, which comprise three distinct, rounded protrusions: a first protrusion 19a, a second protrusion 19b and a third protrusion 19c. The second protrusion 19b is more elongated than the first protrusion 19a and the third protrusion 19c, and is flanked by the first and the third protrusions 19a and 19c. The third protrusion 19a and the third protrusion 19c are positioned symmetrically around the second protrusion 19b, with protrusion 19b in the centre. The centre line of the second protrusion 19b is essentially aligned along an axis being perpendicular to and going through the rotating/pivoting shaft 27 and being aligned with the penetrating member 9. Said axis is also the axis of symmetry for the first and the third protrusions 19a and 19c.

Figure 4A shows the penetrating member 9 of the medical device 3 in a 1st position where it is pointing upwards, deflected 180° from the direction of insertion. The pivoting/rotating shaft 27 is positioned at the upper end 10u of the guiding slot 10. The guiding means 19u and 19l are not in contact with the protrusions 19a, 19b or 19c.

Figure 4B shows the penetrating member 9 of the medical device 3 in a position where it is pointing approximately 135° away from the insertion direction. This position is achieved when applying a downward force onto the top section 14, thereby guiding the pivoting/rotating axis 27 into the direction of insertion, and combining this forward movement with a pivoting, sideward guiding providing a rotating movement (clockwise) of approximately 20°-70°, or around 45°. The pivoting/rotating axis 27 has moved downwards along the guiding means 10, and is now positioned around the upper third of the guiding means 10. The central protrusion 19b is now interacting and/or in contact with guiding means 19u and is located in between guiding means 19u and guiding means 19l. Both protrusion 19a and 19b are interacting and/or in contact with guiding means 19u, which is located in between protrusion 19a and 19b.

Figure 4C illustrates that a further downward force as described above leads to the medical device 3 and device mounting means 18 being pivoted/rotated approximately 90°. In this position, the guiding means 19u and 19l are interacting with the protrusions 19a, b and c. It becomes apparent that the distance between guiding means 19u and 19l is preferably the same or larger than the width of the protrusion 19b. Likewise, the distances between protrusion 19a and protrusion 19b, as well as the distance between protrusion 19b and protrusion 19c are preferably the same or larger than the diameter of the guiding means 19u and guiding means 19l, respectively.

Figure 4D shows that a further downwards force as described above leads to a further pivoting/rotational movement by the action and interaction of the above described guiding means 19u and 19l in combination with the

protrusions 19a, b and c. The rotation stops when the penetrating means are aligned with the direction of insertion, which in the depicted embodiment is after a rotation/pivoting movement of a further 90°, so that the total rotation/pivoting movement is 180°. The final 90° turn is achieved by the interaction of the large protrusion 19b and minor protrusion 19c and the groove between said protrusions with the lower guiding means 19l. As illustrated, a further downwards force in the direction of insertion will lead to a longitudinal insertion of the penetrating member in the desired insertion direction. The length of the longitudinal insertion movement is controlled by the applied downwards force, and the length of the guiding slot 10, where the bottom section of the guiding slot 10l is determining the remaining length of insertion, optionally combined with alternative means (not shown and not described).

Figure 5 illustrates means for protecting and shielding the medical device 3 and its penetrating member 9 from being visible and accessibility. One or more protection means 21 are attached to the inner surface of the insertion device 1 by attachment means 22. Upon activating the insertion device 1, i.e. in the process of insertion of a medical device 3, the protection means 21 are moved from a position, where they are shielding the opening 2 to a position, where they allow passage of the medical device 3. This movement may comprise one or more longitudinal, rotational or pivoting movements, either consecutively or simultaneously or in an overlapping fashion. The required activation means are not shown. In Figure 5 B, the protection means 21 are pivoted upwards, allowing passage of the medical device 3.

Figure 6 shows a cross section of an embodiment of an insertion device 1 according to the invention for inserting a medical device 3. The cross section goes across penetrating member 9 and the length of rotating/pivoting shaft 27, an in direction of insertion, i.e. perpendicular to the surface 60 of the skin.

The various shapes and dimensions, such as thickness and height are depicted schematically. In Figure 6 A, the insertion device 1 is seen ready for application/insertion, with the medical device 3 - comprising body 5 and penetration member 9 - pointing upwards, i.e. away from the patient. The insertion device 1 comprises means for (i) providing a pivoting/rotating movement of the medical device 3, followed by (ii) a longitudinal movement of the medical device 3 into the direction of insertion of the penetrating member 9.

In one embodiment of the invention, the pivoting/rotating movement of the medical device 3 occurs together with a longitudinal movement in direction of insertion. In another embodiment of the invention, rotation means are provided, that provide a rotation/pivoting movement of the medical device 3, independently of a longitudinal movement of the medical device 3 in direction of insertion. In a further embodiment, rotation means are provided, that provide a rotation/pivoting of the medical device 3 from a start position, where the penetrating member 9 is not pointing into direction of insertion, to a second position, where the penetrating member 9 is pointing into the direction of insertion. This rotation/pivoting movement takes place, essentially without longitudinal movement of the medical device 3 into direction of insertion. After completion of rotation/ pivoting movement, i.e. when the penetrating member 9 is aligned in insertion direction, insertion means provide a longitudinal insertion of the penetrating member 9 of the medical device.

In the embodiment illustrated in Figure 6, said insertion device 1 comprises means for providing a pivoting/rotating movement of the medical device 3, as well as a longitudinal movement of the medical device 3. Said means comprise a top section 14 constituting a top part of the device in fig. 6A i.e. when the device is positioned against the patients skin but before insertion, a lower section 16 constituting a lower part in fig. 6A actually touching the patients skin, a pivoting member 31, vertical device mounting means 18v, horizontal device mounting means 18h, a through-going shaft 27, a first

pivoting shaft 41, and a second pivoting shaft 43. Lower section 16, pivoting member 31, and vertical device mounting means 18v comprise each a slot (16s, 31s and 18s, respectively), which are not shown in this Figure. The embodiment of the insertion device is symmetric across the axis defined by the direction of insertion, essentially perpendicular to the surface of the skin 60. Although not depicted as being part of one member, top sections 14 and lower sections 16 can be two separate pieces or parts of the same piece. Also the vertical device mounting means 18v can be two separate pieces or parts of the same piece. Furthermore, the vertical device mounting means 18v and the horizontal device mounting means 18h can comprise one, two or more pieces. In one embodiment, top section 14 and lower section 16 can be of cylindrical shape, similar to the embodiment depicted in Figure 3. Trough-going shaft 27 goes across and connects top section 14, lower section 16, pivoting member 31, and vertical device mounting means 18v. The first pivoting shaft 41 goes through lower section 16 and pivoting member 41. The second pivoting shaft 43 goes through pivoting member 41 and vertical device mounting means 18v. Attachment means for the respective shafts are not shown. In one embodiment, one or more rotating means are provided in order to allow rotation of one or more shafts. In another embodiment, one or more shafts are connected permanently to at least one member of the group comprising top section 14, lower section 16, pivoting member 31, or vertical device mounting means 18v.

In the depicted embodiment the through-going shaft 27 and the first and second pivoting shafts 41 and 43 are parallel to each other, and perpendicular to top section 14, lower section 16, pivoting member 31 and vertical device mounting means 18v. In another embodiment, through-going shaft 27, first pivoting shaft 41 or second pivoting shaft 41 are not parallel to each other. In a further embodiment, at least one or more members selected from the group comprising top section 14, lower section 16, pivoting member 31 and vertical device mounting means 18v are not parallel to at least one other member of said group.

In this embodiment, the order of said means for providing a rotation as well as a longitudinal movement is (from the outside of the insertion device to the inside): top section 14, a lower section 16, a pivoting member 31, vertical device mounting means 18v, horizontal device mounting means 18h. In another embodiment, the order of said means can be different, and the, first and second pivoting shafts 41 and 43 may go through additional sections and or members, and/or through going shaft 27 may not go through all members listed above.

Furthermore, in the embodiment depicted in Figure 6, the insertion device 1 comprises a soft member 61, which is attached at the lower end of lower section 16. The function of soft member 61 is to act as a buffer between the solid parts of the lower section 16 and the surface of the skin 60 of the patient, thereby reducing discomfort for the user. This buffer function can comprise a more uniform distribution of pressure, as well as reducing the discomfort for the patient, when experiencing a device that is colder than body temperature on the skin. In another embodiment of the invention, a soft member 61 can be absent.

In Figure 6 B, the medical device 1 presented in Figure 6 A is now shown in a position, where the medical device 3 has been applied to the patient, and the penetrating member 9, or apart of said penetrating member 9 has penetrated the surface of the skin 60 of the patient. It can be seen, that only lower section 16, pivoting member 31, as well as first and second pivoting shafts 41 and 43 are in essentially in the same position as in Figure 6A. Device mounting means 18v and 18h, thus also medical device 3 have rotated 180° around through-going shaft 27. This is achieved by applying a force by pressing on top section 14, whereby a major fraction of this force is relayed to through-going shaft 27, which then induces a pivoting movement of the pivoting member 31 around the first pivoting shaft 41, thus inducing rotation of the device mounting means18. Buffer member 61 is now shown in a compressed position, and the surface body 5 of the medical device 3 is in contact with the surface of the skin 60 of the patient.

The interactions leading to rotation and longitudinal movement of the device mounting means 18h, 18v and medical device 3 are described in more details in Figure 7 and 8, and the following section of the detailed description.

Figure 7 shows another view of the means of the embodiment of and insertion device 1 presented in Figure 6 (A: top section 14; B: lower section 16; C pivoting member 31; D: device mounting means 18v and 18h). Only a smaller portion of the horizontal device mounting means 18h is presented, and a medical device is not shown. The positions I-VI are:

I: start position;
II: ~45° rotation of device mounting means 18v, 18h;
III: ~90° rotation of device mounting means 18v, 18h;
IV: ~135° rotation of device mounting means 18v, 18h;
V: 180° rotation of device mounting means 18v, 18h;
VI: end position (inserted).

Positions I and VI correspond to the positions depicted in Figure 6 A and B, respectively. The direction of view is from the centre of the insertion device 1, and parallel with through-going shaft 27. The pivoting/rotating movements of the different members become apparent, and their respective distances from the skin surface 60 can be seen. Shapes and outer dimensions of the depicted means are selected arbitrarily for clarity. In a further embodiment, outer section 14 is provided with a handle (not shown), to facilitate application of the insertion device 1.

In Figure 7A it becomes apparent, that by pushing top section 14 downwards, (i.e. in direction of insertion and the patient), through going shaft 27 is pushed down as well. In the depicted embodiment, top section 14 has an opening, as wide or wider as through going shaft 27. It is seen that the through-going shaft 27 is attached towards the lower end (i.e. the end facing the patient). In the depicted embodiment, the shaft is fixed. In another embodiment, it can rotate. Position I is the start position, in which outer section 14 is furthest

away from the surface 60 of the patient. In position VI, outer section14 is closest to the patient.

Figure 7B shows that lower section 16 does not move, and that lower section 16 maintains in contact with surface 60 of the skin of a patient. Six positions of through-going shaft 27 within controlling slot 16s are seen (I-VI). Towards the upper end of the lower section 16, above the controlling slot 16s, an opening is provided for attaching the first pivoting shaft 41. In the depicted embodiment, the opening is wider than the diameter of the first pivoting shaft 41, and said first pivoting shaft 41 can rotate within said opening. In another embodiment, the first pivoting shaft 41 cannot rotate. In direction of insertion, a controlling slot 16s is provided parallel to the direction of insertion within lower section 16. Through-going shaft 27 is encompassed by said controlling slot 16s, and controls the length of movement of the top section 14, as top section 14 and through-going shaft 41are attached. The length of the slot is longer than the length of insertion.

Figure 7C shows that pivoting member 31 comprises a guiding slot 31s, in which through-going member 27 can move is up and down. Above guiding slot 31s, a first pivoting shaft 41 is provided, and pivoting member 31 can pivot/rotate around pivoting axis 41. In one embodiment, first pivoting shaft 41 is attached to lower section 16, and pivoting member 31 comprises an opening or bearing for pivoting axis 41. In another embodiment, first pivoting shaft 41 is attached pivoting member 31. Guiding slot 31s is straight, apart from a bended start section. Guiding slot 31s is sufficiently bended, so that a second pivoting shaft 43 can be provided, said second pivoting shaft 43 being positioned essentially in line between pivoting axis 41, the upper start point of guiding slot 31s and the straight lower section of guiding slot 31s. It becomes apparent that pushing outer section 41 downwards leads to a downwards movement of through-going shaft 27, guided longitudinally downwards by controlling slot 16s of the lower section 16. Pivoting member 31 is connected with the lower section 16 through the first pivoting shaft 41. The downwards movement of through-going shaft 27 leads to a pivoting

movement of pivoting member 31 (position II), which reaches its maximum at position III, where the guiding slot 31s is most bend away from the straight line between start and end point of guiding slot 31s. A further downwards movement bottom leads to reduction of pivoting (position IV). When the through-going shaft reaches the straight lower section of guiding slot 31s and moves downwards, the pivoting movement of pivoting member 31 has stopped (position V -VI).

Figure 7D shows the rotation and longitudinal movement of the horizontal and vertical device mounting means 18h and 18v from start position I to inserted position VI. The vertical device mounting means 18v point upwards in position I and downwards, i.e. towards the surface of the skin of a patient, in position V and VI. Horizontal device mounting means 18 comprise a longitudinal guiding slot 18s for second pivoting shaft 43, and an opening wide enough to encompass through-going shaft 27. Downwards movement of through-going shaft 27 provides a pivoting movement of pivoting member 31, thus also pivoting movement of the second pivoting shaft 43. In position II it is seen, that this in turn provides a rotation/pivoting movement of the horizontal and vertical device mounting means 18h and 18v. In position III, the vertical device mounting means 18v and 18h have turned approximately 90°, approximately 135° in position IV, and ~180° in positions V and VI. It becomes apparent the rate of turn is essentially determined by the angle between through-going shaft 27 and second pivoting shaft 43 (compare Figure 7 C and 7 D). The distances between through-going shaft 27 and second pivoting shaft 43 are varying during positions I to VI. The length of guiding slot 18s is longer than the length of insertion (difference between positions V and VI).

Figure 8 shows a further view of the embodiment of an insertion device at the 6 different positions (I-VI) presented above in Figure 7. The direction and view of the cross sections match the cross section presented in Figure 6 A and Figure 6 B, corresponding to positions I and VI in Figure 7, respectively.

Claims

1. An inserter device (1) for inserting a penetrating member (9) into the subcutaneous area and/or intramuscular area of a patient, said inserter device (1) comprising a housing (15) encompassing said penetrating member (9), said housing comprising a top section (14) and a lower section (16), wherein said insertion device (1) comprises pivoting means (27, 31, 41, 43) and guiding means (10, 19, 16s, 31s, 18s) providing one or more pivoting movement(s) of the penetrating member (9) from a first position, where the penetrating member (9) is not pointing into the direction of insertion, to a second position, where the penetrating member (9) is aligned with the direction of insertion, to a third position, where the penetrating member (9) protrudes the housing (15) and the penetrating member (9) is aligned in the direction of insertion, **characterized in** that said guiding means (10, 19, 16s, 31s, 18s) are adapted to provide a longitudinal movement of the penetrating member (9) from said second position to said third position.

2. An inserter device according to any of the preceding claims, where said pivoting and guiding means (19, 27, 31, 41, 43, 10, 16s, 31s, 18s) provide a fourth position by a longitudinal movement where the penetrating element (9) is fully inserted in the patient, said longitudinal movement being of the same length or longer than the length of the penetrating member (9).

3. An inserter device (1) according to any of the claims 1-2, wherein said pivoting means comprise one or more shafts (27).

4. An inserter device (1) according to claim 3, wherein a shaft (27) traverses the top section (14) and the lower section (16).

5. An inserter device (1) according to claim 4, wherein the shaft (27) consists of one through-going member.

6. An inserter device (1) according to claim 4, wherein the shaft (27) consists of two or more pieces.

7. An inserter device (1) according to claim 5 or 6, wherein device mounting means (18) are attached to said shaft (27), and device mounting means (18) and shaft (27) share the same center of rotation.

8. An inserter device (1) according to any of the preceding claims, wherein said pivoting means comprise one or more pivoting shafts (41, 43) and one or more pivoting members (31).

9. An inserter device (1) according to claim 8, wherein a first pivoting shaft (41) traverses the lower section (16) and a pivoting member (31), and the first pivoting shaft (41) is the centre of rotating of said pivoting member (31).

10. An inserter device (1) according to claim 9, wherein a second pivoting shaft (43) traverses the pivoting member (31) and the device mounting means (18).

11. An inserter device (1) according to any of the previous claims, wherein said guiding means comprise one or more guiding slots (10, 16s, 18s).

12. An inserter device (1) according to claim 11, wherein said guiding slot (10, 16s) is provided on the lower section (16), said guiding slot (10, 16s)

being parallel to the direction of insertion, and being of the same length or longer than the length of said longitudinal movement.

13. An inserter device (1) according to claim 12, wherein said guiding slot (10, 16s) is encompassing said shaft (27), and is restricting the length of the longitudinal movement of the shaft (27) and the lower section (14).

14. An inserter device (1) according to any of the previous claims, wherein the guiding slot (31s) is provided within a pivoting member (31), said guiding slot (31s) comprising a bend section towards the upper part of the pivoting member (31), and a straight section of the same length or longer than the length of said longitudinal movement, said guiding slot (31s) encompassing and restricting the movement of said shaft (27).

15. An inserter device (1) according to any of the previous claims, wherein the guiding slot (18s) is provided within a vertical section (18v) of said device mounting means (18), the guiding slot (18s) is of the same length or longer than the length of said longitudinal movement, said guiding slot (18s) encompassing the second pivoting shaft (43), and restricting the movement of the second pivoting shaft (43).

16. An inserter device (1) according to any of the preceding claims, wherein application of a downward force on the top section (14) into the direction of insertion provides a rotation of the medical device (3) through interactions of the shaft (27) being guided by the guiding slot (16s) of the lower section (16) and the guiding slot (31s) of the pivoting member (31), and through interactions of the first and second pivoting shafts (41, 43) being guided by the pivoting member (31) and guiding slot (18s) on the vertical section (18v) of the device mounting means (18).

17. An inserter device (1) according to any of the claims 7-15, wherein said guiding means (19) comprise one or more rounded protrusions (19a, 19b, 19c) provided on said device mounting means (18), said protrusions (19a, 19b, 19c) extending away from the direction of insertion.

18. An inserter device (1) according to claim 17, wherein said guiding means (19) comprise a major protrusion (19b) flanked symmetrically by two minor protrusions (19a, 19c), said major protrusion (19b) being aligned with the penetrating member (9) along an axis perpendicularly to the shaft (27).

19. An inserter device (1) according to claim 17 or 18, wherein the device comprises upper guiding means (19u) and lower guiding means (19l), and said upper and lower guiding means (19u, 19l) are extending from the inner surface of the lower section (16).

20. An inserter device (1) according to any of the claims 17 to 19, wherein the interaction between the protrusions (19b,19a, 19c) and the upper and lower guiding means (19u, 19l) provides a rotation of the medical device (3) upon application of a downward force on the top section (14).

21. An inserter device according to any of the preceding claims, where the penetrating member (9) comprises a cannula (11) and/or an introducer needle (13).

22. An inserter device according to claim 21, where the introducer needle (13) is part of the inserter device, and where said introducer needle (13) is removed from a medical device (3) after insertion of the penetrating member (9).

23. An inserter device according to claim 22, where said pivoting and guiding means (27, 31, 41, 43, 10, 16s, 31s, 18s,19) provide a fifth position by a longitudinal movement, optionally accompanied by a pivoting or rotational movement, where the introducer needle (13) is retracted through the penetrating member (9).

24. An inserter device according to claim 23, where said pivoting and guiding means (19, 27, 31, 41, 43, 10, 16s, 31s, 18s) provide a fifth position by one or more linear movements and one or more pivoting movements, where the needle (13) is retracted into the housing (15).

25. An inserter device according to claim 22 or 23, where the introducer needle (13) is no longer visible after retraction into the housing (15).

26. An inserter device according to any of the preceding claims, where the penetrating member (9) is a part of a medical device (3).

27. An inserter device according to any of the preceding claims, where the medical device (3) is a sensor, or an infusion part, or a gateway/port for injection of a fluid.

28. An inserter device according to any of the preceding claims, where the inserter device is for single use (disposable).

29. An inserter device according to any of the preceding claims, where the inserter device is suitable for repeated use.

30. An inserter device according to any of the preceding claims, where the inserter device is suitable for inserting different medical devices, either simultaneously or consecutively.

31. An inserter device according to any of the preceding claims, where the inserter device can be cleaned, disinfected and/or sterilized before, after or in between uses.

32. An inserter device according to any of the preceding claims, where the penetration member (9) is "in center" or "off center" of the inserter device.

33. An inserter device according to any of the preceding claims, where the insertion device (1) comprises additional cover and/or protection means (4, 21).

34. An inserter device according to any of the preceding claims, where the central axis of insertion is parallel to the central axis of the insertion device.

35. An inserter device according to any of the preceding claims, where the central direction of insertion of the penetrating member (9) is either essentially perpendicular to the patient's skin surface, i.e. at an insertion angle α_{ins} around 0°, or at an insertion angle $0° < \alpha_{ins} < 90°$, or $10° < \alpha_{ins} < 80°$, or $20° < \alpha_{ins} < 70°$.

36. An inserter device according to any of the preceding claims, where the center axis of the inserter device is essentially perpendicular to the patient's skin surface, i.e. at center axis angle α_{center} around 0°, or at an center axis angle $0° < \alpha_{center} < 90°$, or $10° < \alpha_{center} < 80°$, or $30° < \alpha_{center} < 60°$.

37. An inserter device according to any of the preceding claims, where the direction of insertion of the penetrating member (9) is either parallel to the center axis of the inserter device, i.e. at a deflection angle $\alpha_{defl} = 0$, or at a deflection angle $0° < \alpha_{defl} < 90°$, or $10° < \alpha_{defl} < 80°$, or $30° < \alpha_{defl} < 60°$.

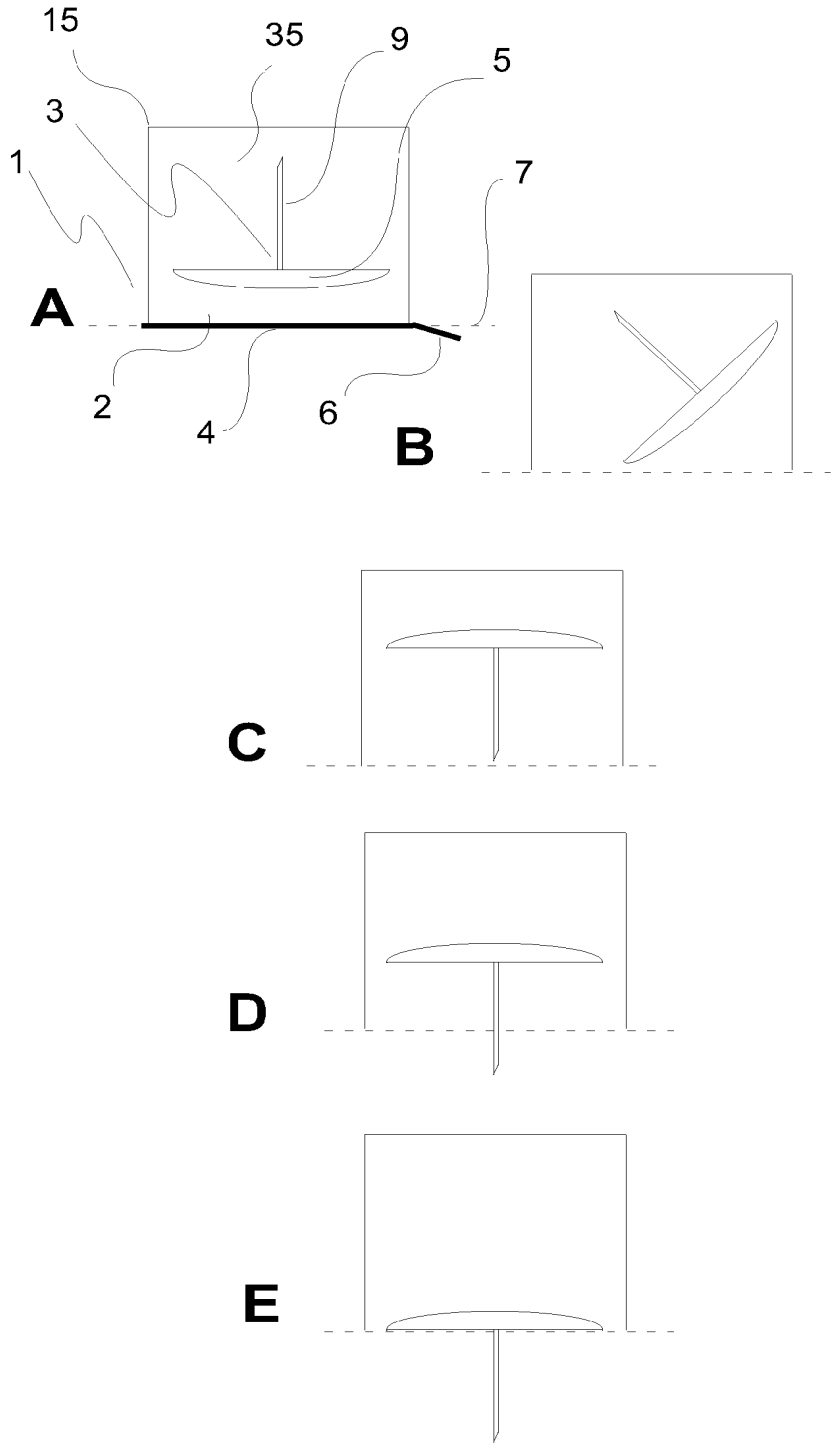

Fig. 1

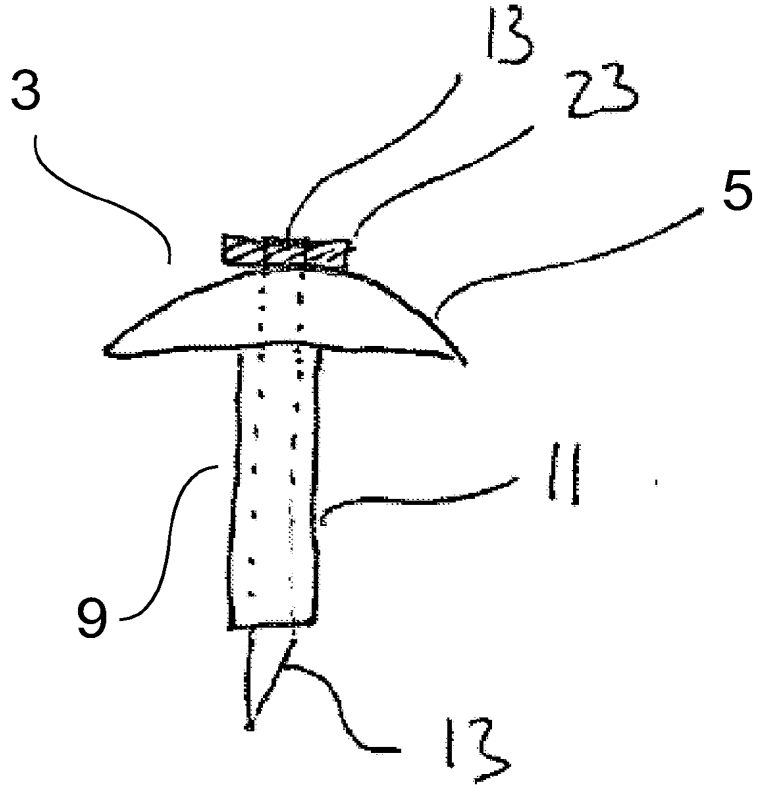

Fig. 2

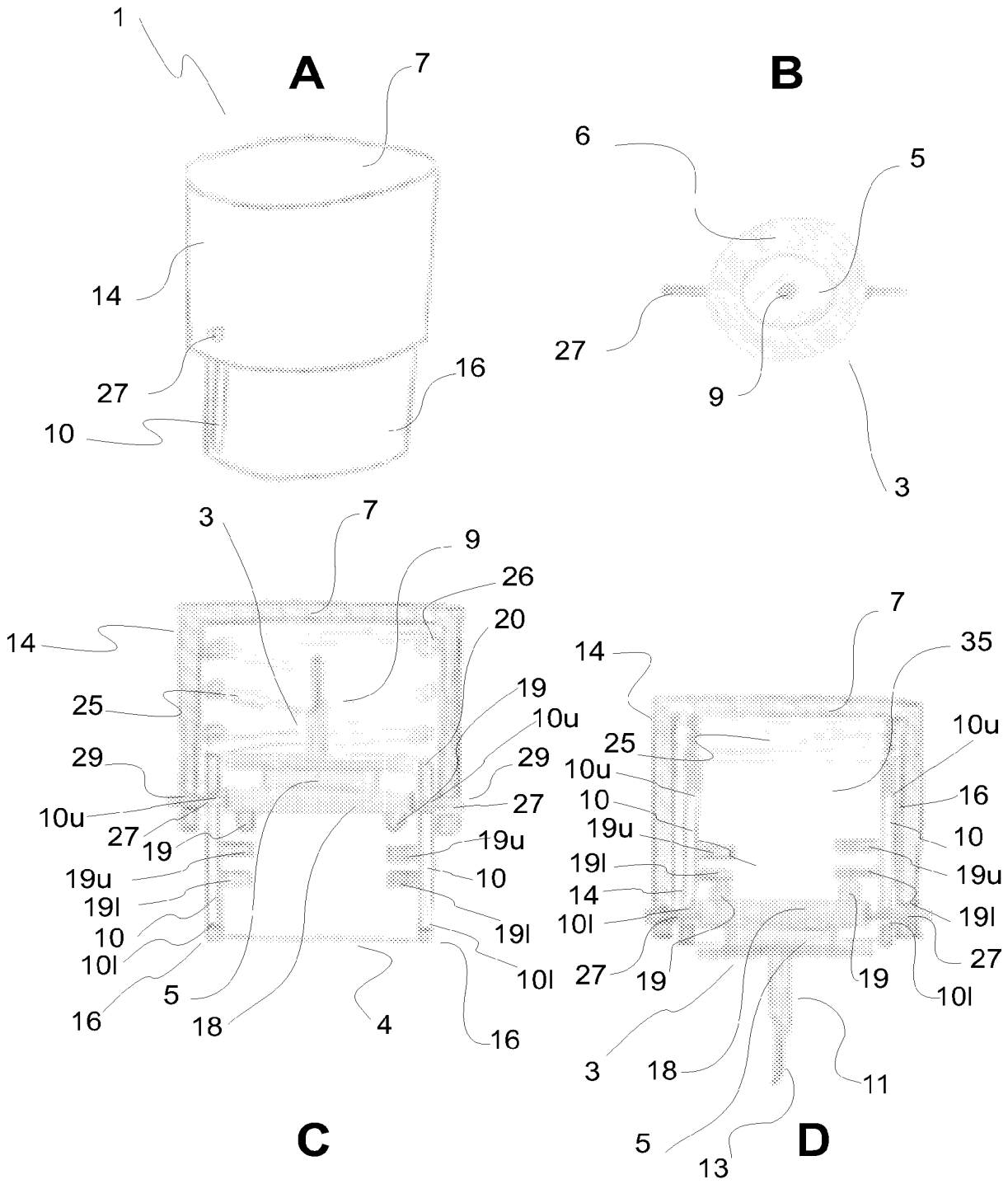
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Fig. 3

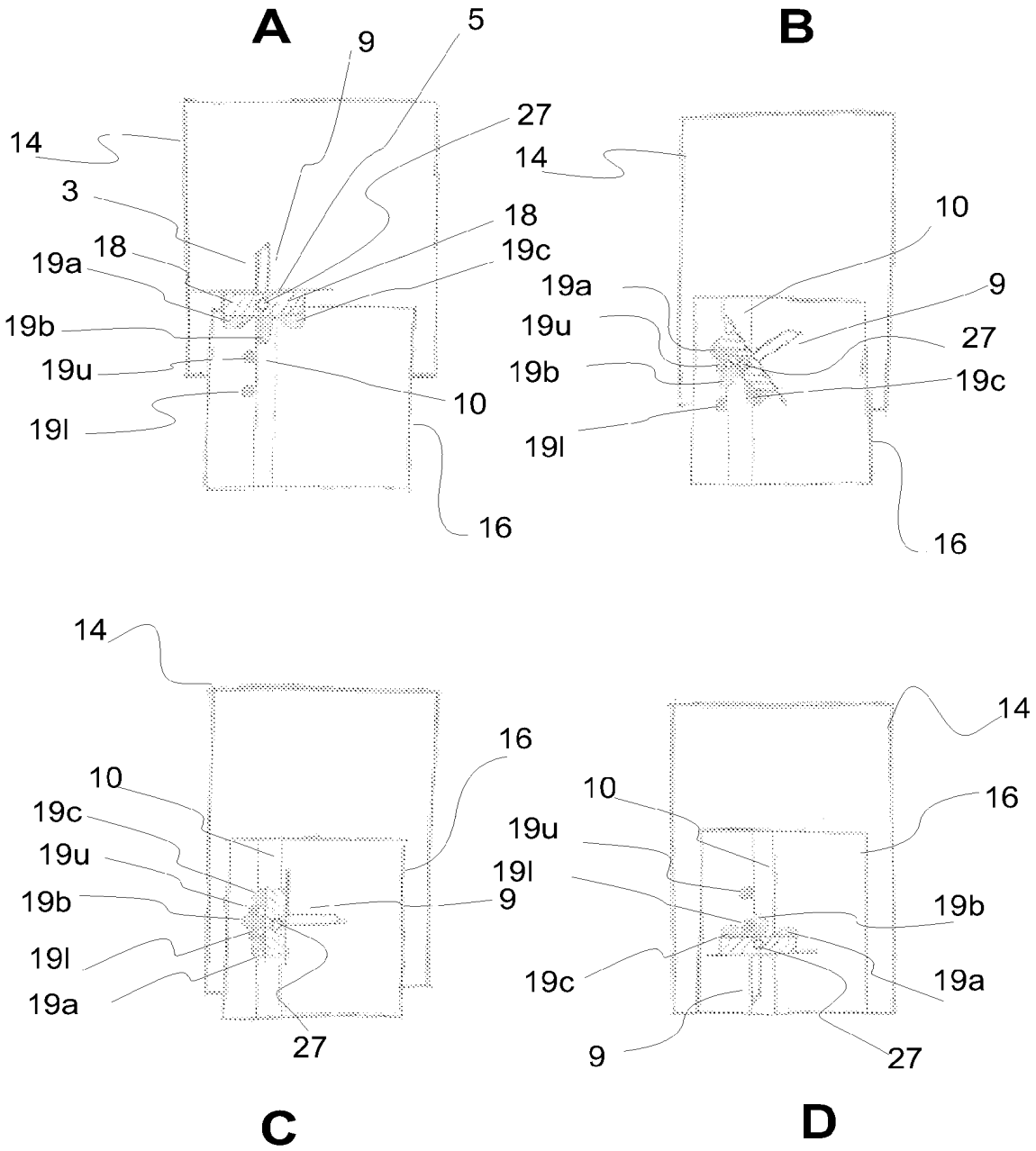
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Fig. 4

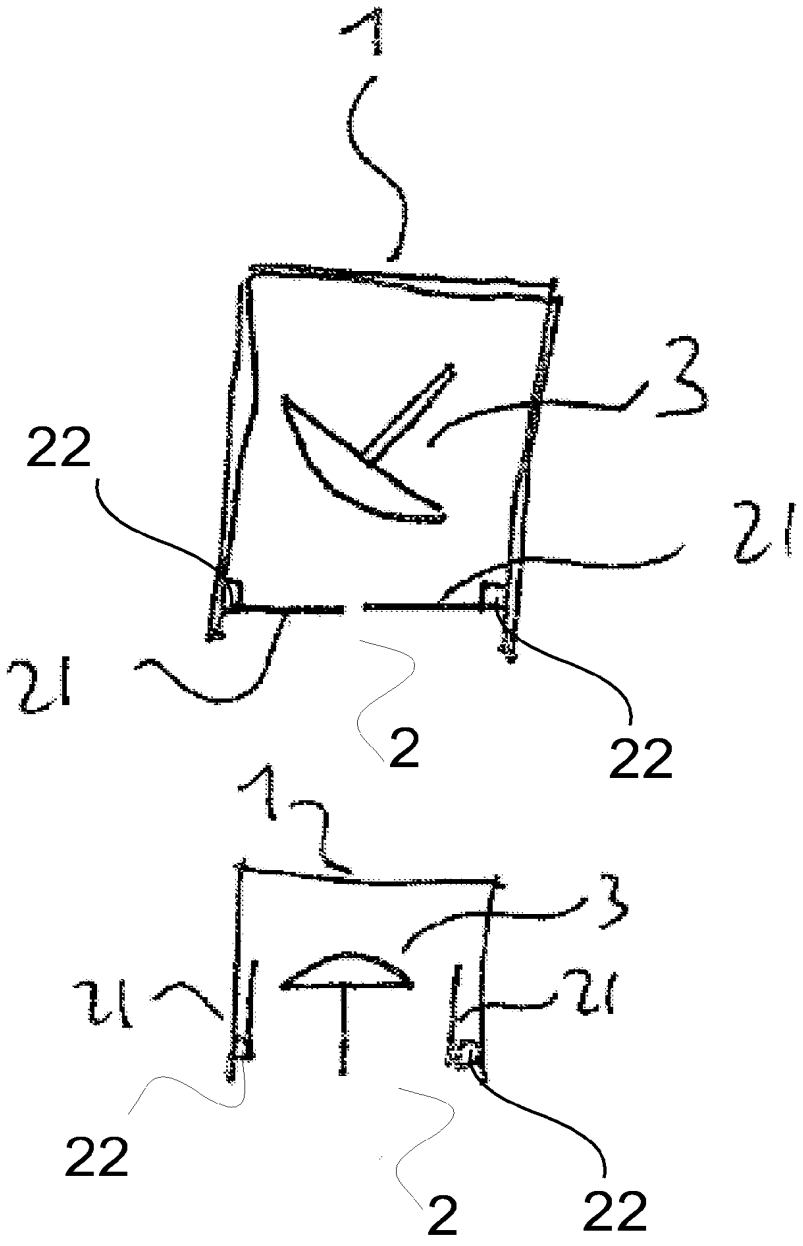

Fig. 5

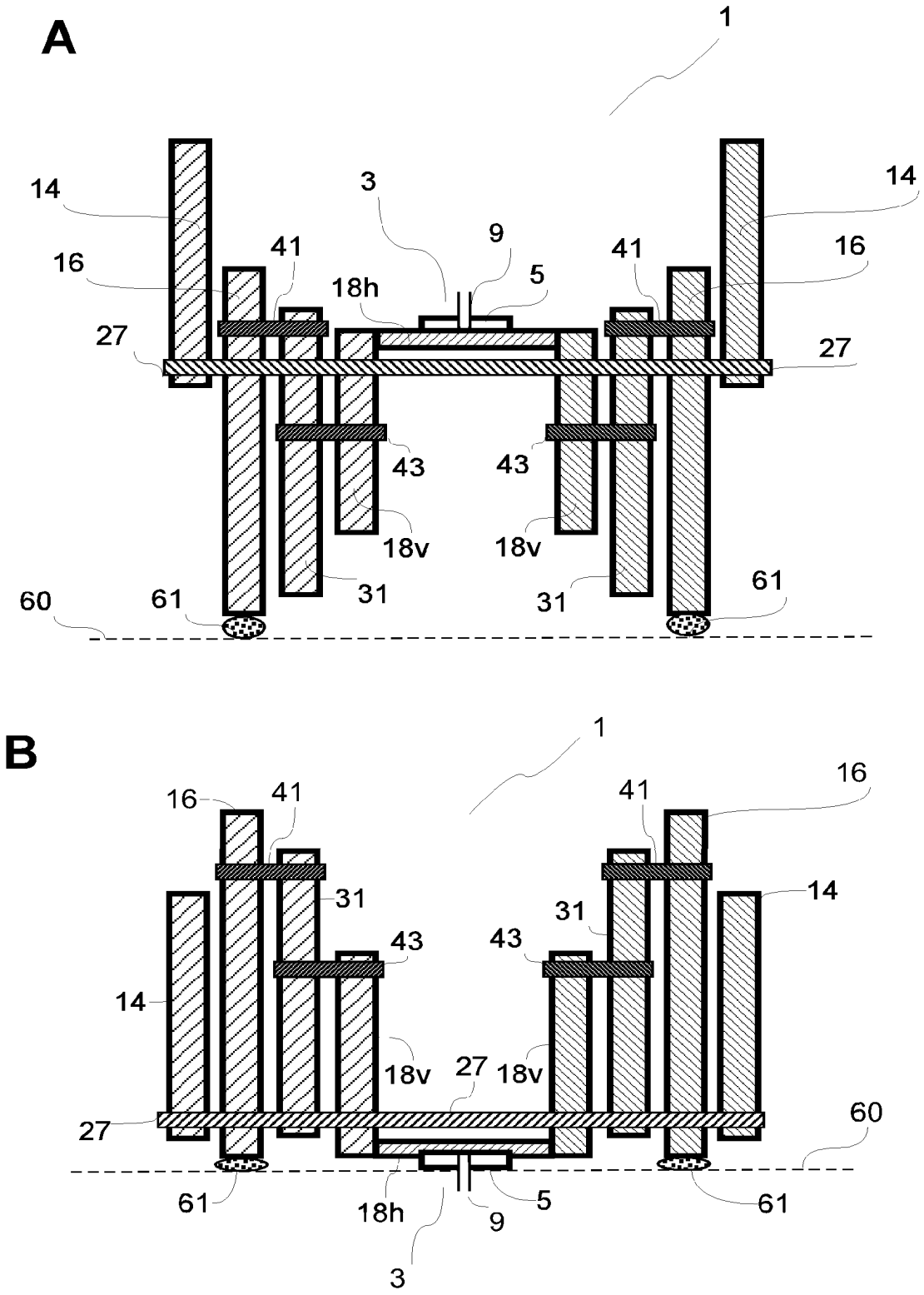
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Fig. 6

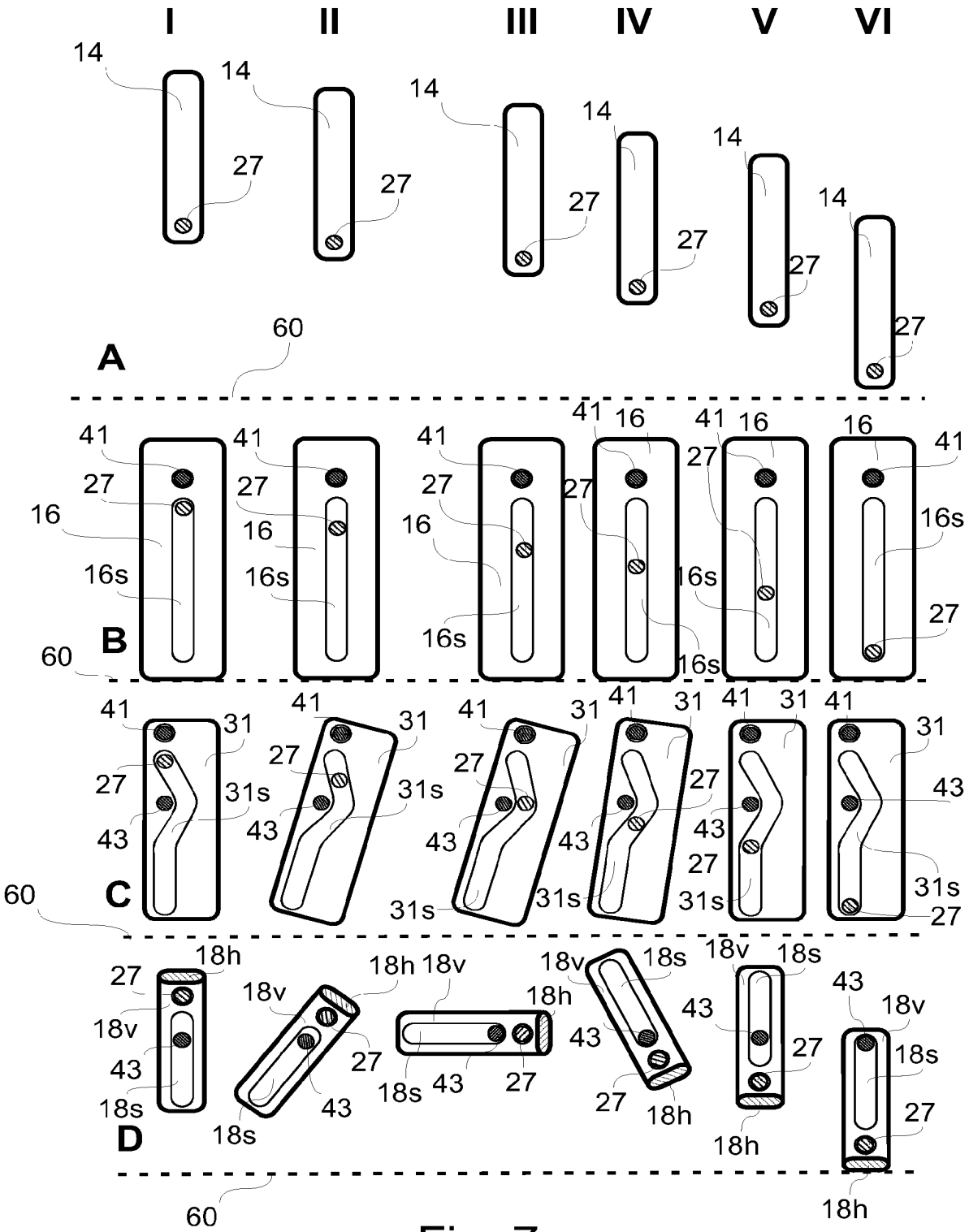
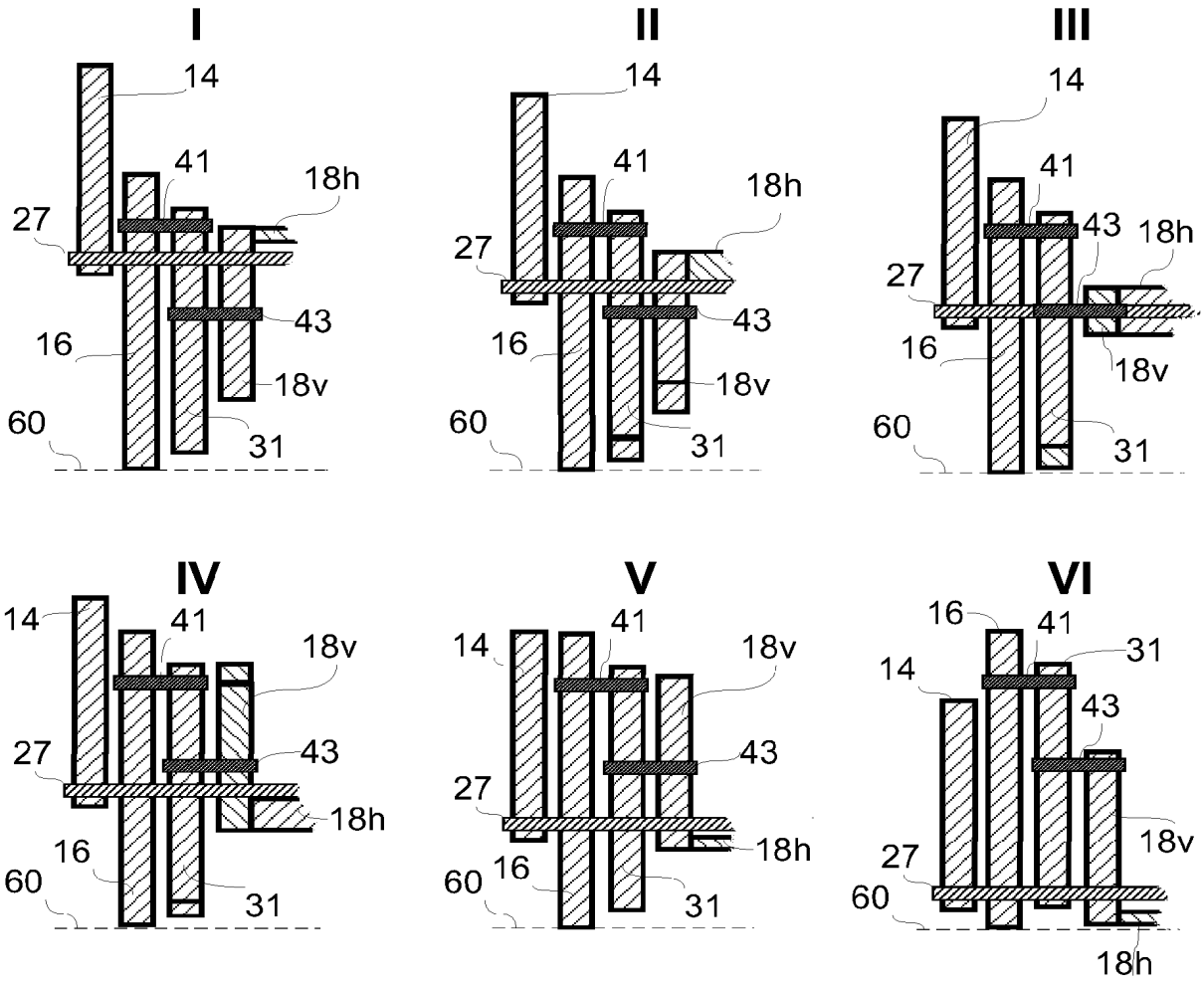


Fig. 7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VI
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41
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Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/058586

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/158 A61M5/32 A61M25/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 1 502 613 A (NOVO NORDISK AS [DK]) 2 February 2005 (2005-02-02) figures 1-7 paragraph [0043] - paragraph [0072]	1-5,7,8, 11,21, 22,26-37 6,9,10, 12-20
X	US 5 858 001 A (TSALS IZRAIL [US] ET AL) 12 January 1999 (1999-01-12) figures 1-21 column 8, line 16 - column 14, line 44	1,3,8, 11, 21-29, 31-37
X	US 2005/215979 A1 (KORNERUP GRETE [DK] ET AL) 29 September 2005 (2005-09-29) figures 1-36 paragraph [0085] - paragraph [0117]	1-5,11, 21-37

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 October 2008	17/10/2008

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1502613 A	02-02-2005	WO 2005011779 A1	10-02-2005
		EP 1654019 A1	10-05-2006
		US 2007049865 A1	01-03-2007
US 5858001 A	12-01-1999	NONE	
US 2005215979 A1	29-09-2005	CA 2560784 A1	06-10-2005
		CA 2560788 A1	06-10-2005
		WO 2005092410 A1	06-10-2005
		WO 2005092411 A1	06-10-2005
		EP 1727576 A1	06-12-2006
		EP 1727577 A1	06-12-2006
		JP 2007530105 T	01-11-2007
		JP 2007536946 T	20-12-2007
		KR 20060128005 A	13-12-2006
		KR 20060131888 A	20-12-2006
		US 2008039794 A1	14-02-2008
		US 2008119792 A1	22-05-2008